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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/945,425	10/21/97	CEDERBERG C	1103326-282

EXAMINER: DESAI, R

ART UNIT: 1625 | PAPER NUMBER: 18

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007470
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

Office Action Summary

Application No.	Applicant(s)
08/945,425	Cederberg Christer et al
Examiner	**Group Art Unit**
Rita D sai	1625

☒ Responsive to communication(s) filed on *Jan 9, 2001*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-11, 15, 16, 18-21, and 23-25* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-11, 15, 16, 18-21, and 23-25* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *16*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Continued Prosecution Application

The request filed on 1/9/2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/945,425 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 12-14 and 17 have been canceled.

Claims 1-11,15,16,18-21, 23-25 are pending.

Lack of Unity

Restriction is required under 35 U.S.C. 121 and 372.

The restriction set forth in paper # 5 is maintained. During a telephone conversation with Mr. John Genova on April 21 1999 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-11, 15,16,18 and 19 drawn to administration regimen, pharmaceutical formulations and method of treating ,

The elected group is

Group I , claims 1-11, 15,16,18-21,23-25 drawn to administration regimen, pharmaceutical formulations and method of treating , wherein Het1 is a substituted pyridine, and Het2 is a benzimidazole classified in Class 546 and 514 and Subclasses 273.4 and 339.

Lack of Unity was made on claims drawn to an improper markush group with only -S=O as its common core. This is not a substantial common core with a special technical feature of treating diseases, hence under the rule of lack of unity the claims have been divided into various groups.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant preserves the right to file a divisional on the canceled non-elected subject matter , without prejudice, in due course.

Claim Rejections - 35 USC § 102

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-11, 15,16,18-21,23-25 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Bergstrand et al US 5,753,265.and 5,817,338.

Berdstrand et al '265 discloses the compounds of formula 1 wherein Het 1 is a pyridine and Het 2 is a benzimidazole their alkaline salts and enantiomers and their use as H+K+-ATPase inhibitors. See formula I , claim 2 columns 19 and 20; lines 20-60 of col. 1, lines 33-63 of col. 5, lines 9-15 of col. 7. Also see whole document.

The claim one discloses a composition with the same active ingredient as that of the instant application as given in claim 2 of the reference.The reference also discloses the other non-elected groups of compounds also.

Bergstrand et al '265 discloses the pharmaceutical multiple unit tableted dosage of compound of formula 1 wherein Het 1 is a pyridine and Het 2 is a benzimidazole or its single enantiomer.(See the whole document, lines 4-17 of column 1 and claims 1-3,17, 18,21 and 22 of US. 5,753265)

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11, 15,16,18-21, 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bregstrand et al US 5,753,265 and 5817,338.

Scope and Content of Prior Art MPEP 2141.01

Berstrand et al '265 teaches the compounds of formula I or its single enantiomer wherein Het 1 is a pyridyl and Het 2 is a benzimidazole , used as H^+ , K^+ ,ATPase inhibitors for gastric disorders.

Difference between Prior Art and Claims MPEP 2141.02

The difference between the reference and the instant is that it the reference these compounds are present as a composition covered by an one enteric coating having mechanical properties, but the active ingredient is the same.

Prima Facie Obviousness, Rational and Motivation MPEP 2142-2413.

On e skilled in the art would find it obvious and have a reasonable expectation of success at using the active ingredient for medicinal use .

Claims 1-11, 15,16,18-21,23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tyers B. US 5330982.

Scope and Content of Prior Art MPEP 2141.01

Tyers ' 982 teaches the use of Omeprazole as H^+ , K^+ ATPase inhibitor. It also teaches the use of oral administration suitably formulated to give controlled release.(See lines 53-56 of column 10, lines 42-43 and 60- 66 on column 2 of the reference.)

Difference between Prior Art and Claims MPEP 2141.02

The difference between the reference and the claimed invention is that the reference is silent about the blood plasma profile.

Prima Facie Obviousness, Rational and Motivation MPEP 2142-2413.

A person of ordinary skill in the art would have a reasonable expectation of success and be motivated to collect blood concentrations to test the extended release of the active ingredient.

Claims 1-11,13, 18-21, 23-25 are rejected under 35 U.S.C. 103 as being unpatentable by Bergstrand et al US 5,753,265, in view of Sachs et al, US 5,945,124, Pharmaceutics, Science of Dosage Form Design. And T. Lind et al, Gut 1983, pages 270-276 and T. Lind et al , pages 1259-1266.

Scope and Content of Prior Art MPEP 2141-.01

Bergstrand teaches the compounds , oral formulations, and method of using the compounds of the claimed invention. Except that it does not specifically mention extended blood plasma profile. See whole document specially lines 33-38 of column 5. But, multiple layered tablets inherently would give an extended release of dosage. See Sachs et al US 5,945,124, lines 30-35 of column 3. Thus with an extended release it is inherent that it would give an extended blood plasma profile.

Difference Between Prior Art and Claims MPEP 2141.02

The reference does not specifically mention extended blood plasma profile.

Prima Facie Obviousness , Rational and Motivation MPEP 2142- 2413

A person of skill in the art would have a reasonable expectation and be motivated to use extended release tablets, or other formulation to obtain an extended blood plasma profile, since it is well known that the effect of H+,K+ATPase inhibitors diminishes after a few hours . See references T. Lind et al , pages 1259- 1266, Tore Lind et al , Effect of Omeprazole, Gut. 1983, pages 270-276.

Sach et al teaches pantoprazole, which is one of the H+,K+ATPase inhibitors. It would have been obvious to use the same concept for other H+,K+ATPase inhibitors like omeprazole.
The Science of Dosage Form Design from Pharmaceutics teaches different ways and pro and cons of making and using sustained release tablets and formulations. See page 315 of the article.
The compounds according to Berstrand along with the teachings of Sach's'124 , one of skill in the art would extend the principles of pantoprazole, to other H+,K+ATPase inhibitors, like Omeprazole etc.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Desai whose telephone number is (703) -305-1868. The examiner can normally be reached on Monday to Friday from 8.00 am to 4.30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner , Mr. Alan Rotman, can be reached on (703) 308-4698.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-1235 .

R.D.

Feb. 21st. 2001.

Alan L. Rotman

ALAN L. ROTMAN
PRIMARY EXAMINER